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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,898	02/17/2000	Kirti Dave	065733/2262	7146

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	33

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/505,898	DAVE ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-92* is/are pending in the application.

4a) Of the above claim(s) *48-53,57-59,66-71 and 82-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-47,54-56,60-65,72-81 and 88-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

The Amendment filed March 4, 2003 (Paper No. 32) in response to the Office Action of August 27, 2002 is acknowledged and has been entered. Claims 63-92 have been added. Claims 44-47, 54-56, 60-65, 72-81, 88-92 are pending and are currently being examined. Claims 48-53, 57-59, 66-71, 82-87 are drawn to non-elected subject matter set out in the election restriction requirement of Paper No. 8 and reiterated in Paper No. 24. Applicant is herby advised that the newly added claims 66-71 and 82-87 make reference to Togaviridae and Flaviviriadae, these represent two different families of virus as set out in Fields Virology. Therefore, a Togavirus belongs to a different family and cannot be further defined as being a Flavivirus.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

New corrected drawings are required in this application because drawings and photographs submitted February 4, 2002 fail to comply with 37 CFR 1.84. Please see the Draftsperson's review form PTO-948 (attached to Paper No. 29). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification

Claim Rejections - 35 USC § 103

The rejection of claim 44-46, 54-56, 60-62 and newly added claims 63-65,72-81 and 88-89 under 35 U.S.C. 103(a) over Oprandy et al. (Journal of Clinical Microbiology, 1990, see IDS #5), Huang et al. (U.S.Pat. No. 5,712,172) and WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5) **is maintained** for reasons of record.

The instant invention is drawn to a method of analyzing an arthropod sample for an agent that may cause disease in humans. The method (claim 44) contains the following steps: (a) obtaining the arthropod sample, (b) treating the sample to expose the analyte from the arthropod, (c) contacting the liquid permeable support which contains a capture reagent with the sample from the previous step (d) allowing liquid to flow vertically through the support by capillary action, and (e) detecting the presence of the analyte. The claims contain the following additional limitations: the detection moiety, the placement of the analyte specific reagent, the arthropod is a mosquito, the liquid permeable support contains a control area, the analyte specific reagents are monoclonal antibodies, or gold and latex labeled antibodies. The newly added claims add that the arthropod sample is contacted with a dipstick or that a panel assay is applied.

Applicant's arguments are that Oprandy et al. teaches "that the use of brittle nitrocellulose in membrane based tests is undesirable because of the possibility of high background" ...thus Oprandy teaches away from nitrocellulose-based membrane tests.

According to applicants "Huang teaches the use of nitrocellulose for the porous material to achieve adequate mechanical strength critical for providing favorable test results and Organdy teaches away from the use of nitrocellulose because of high backgrounds." Applicant's cite *In re Gurley* 27 F3d 551, 31 USPQ2d 1130 (CA FC 1994) that a prior art teaching may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference. Applicant's additionally argue that the samples used in the cited references all differ which implies a lack of motivation in the general knowledge of the art. Applicant additionally argues that the extra step in claim 44 as not being taught by the prior art.

Applicant's argument's have been fully considered but are not deemed persuasive. Applicant's arguments are that non-preferred embodiments cannot be used to make a 35 U.S.C. 103 obvious type rejection. The court has not found this to be the case, see *In re Lamerti and Konort* 192 USPQ 278, 280 (CCPA 1976), "....is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments must be considered."

In re Gurley (CA FC) 31 USPQ2d 1130 (cited by Applicant)

> Page 1131: Referring to the statement of inferiority in the Yamaguchi reference, Mr. Gurley argues that Yamaguchi "teaches away" from Gurley's invention. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. *See United States v. Adams* , 383 U.S. 39, 52, 148 USPQ 479, 484 (1966)
>
> Page 1132: Gurley's position appears to be that a reference that "teaches away" can not serve to create a *prima facie* case of obviousness. We agree that this is a useful general rule. However, such a rule cannot be adopted in the abstract, for it may not be applicable in all factual circumstances. Although a reference that teaches away is a

> significant factor to be considered in determining unobviousness, the nature of the teaching is highly relevant, and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.

In re Lamerti and Konort and *In re Gurley* both indicate that the use of a non-preferred embodiment in the prior art does not render the product unobvious. Applicant's invention is claiming the use of antibodies to detect disease agents in an arthropod sample using a device, such as a dipstick, which can be made up of nitrocellulose or any other porous material.

Oprandy et al. indicates that nitrocellulose is a functional substance in a membrane-based test, the reference does not indicate that the membrane cannot be used. Oprandy et al. teach a dot-blot immunobinding assay to detect arthropod-borne agents. The method includes isolating the sporozoite from the mosquito, treating the sporozoite with a detergent to expose the analyte (see materials and methods). Alternately, sporozoite containing mosquitoes were homogenized together in the presence of detergent before spotting onto the filter. An antibody to detect the circumsporozoite protein was used to assay for the presence of the etiologic agent (see figure 2). The titration of the arthropod vector with SDS liberates the antigen. The references also teaches that this same technique can be used for other arthropod –vectored etiologic agents (see page 1703, column 2, last paragraph). The reference does not teach applying the sample to a dipstick device for the detection of the analyte.

Huang et al. teach the use of a lateral flow device for the detection of an analyte in a single step. It is important to point out that latter flow does not equate to horizontal, nowhere in the patent is there any reference as to the positioning of the device during the detection phase. Lateral flow in the scope of the patent refers to the side-to-side movement of the liquid that is applied to the porous material, such as nitrocellulose. The reference does not limit the material

to nitrocellulose and can be any material that allows lateral flow (see column 5, lines 12-23). Capillary flow is the result of surface tension. It is the surface tension that moves water through the material; this is regardless of the positioning of the device vertical/horizontal as the water will move from the wetted area to the dry area by way of wicking action. The Huang et al. device contains a sample receiving region which is in direct contact with the liquid sample that contains the analyte, a separate analyte detection region and an end flow region all made of porous material which wicks the liquid through the analyte detection region (see Huang et al. claim 1). The analyte detection region includes labeling reagents, a capture reagent and a control reagent. The device can be used for the detection of analytes directly from a biological sample. The reference teaches a method of setting up the test strip, using the appropriate controls and utilizing colored detection agent. The physical construction of the device is the same as the instantly claimed dipstick. The reference also teaches the various detection moieties that can be used with the analyte detection reagent. The reference does not teach detecting an etiologic agent from a mosquito sample.

WHO Bulletin teaches a dipstick assay for the detection of a malarial antigen found in the blood of an infected patient. Here the following steps are used: a blood sample is collected, then the blood is mixed with a lysing agent, the dipstick is placed vertically in the sample and the sample is rapidly taken up by capillary action, a detection agent is then added to sample well, the dipstick is washed and the dipstick is analyzed for the presence of a positive reaction (see figure 1 and page 48 column 2, last paragraph). The dipstick construction contains a reagent control as well. The method steps do not require a prefiltration step of the sample to remove cell debris from the whole blood lysates. The reference teaches the detection of a blood stage malarial

antigen, the reference does not teach the detection of a mosquito stage antigen from a mosquito sample.

It remains the Office's position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the analyte detection reagents as taught by Oprandy et al. and apply them to the device taught by Huang et al. and the WHO bulletin. One having ordinary skill in the art would have been motivated to do this because in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for these etiologic agent. This information is important to assess the efficacy of insect control and abatement programs. One having ordinary skill in the art would have a high expectation of success in applying the antibodies and the methods of exposing the analyte using detergents as taught by Oprandy et al. and formulate them into the device as taught by Huang et al. and the WHO Bulletin. Therefore, the instant invention is obvious over Oprandy et al., Huang et al. and the WHO Bulletin.

The rejection of claim 44-46, 47, 54-56, 60-62 and newly added claims 63-65,72-81 and 88-89 under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS), Huang et al. (U.S.Pat. No. 5,712,172) and WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5) in view of Rattanarithikuln et al. (American Journal of Tropical Medicine, 1996, from applicant's IDS) and Sithiprasasna et al. (Annals of Tropical Medicine and Parasitology, from applicant's IDS) **is maintained** for reason of record.

Applicant's arguments and the Office's response are essentially the same as those set out in the above rejection. Applicant further argues that neither Rattanarithikuln et al. or Sithiprasasna et al. teach or motivate the selection of monoclonal antibodies for the detection of arthropod-borne disease vectors. This is not found convincing because Rattanarithikuln et al. teach using monoclonal antibodies in ELISA detection assay (see page 116, 3rd paragraph). Sithiprasasna et al. teach using monoclonal antibodies for the detection of Dengue virus a flavivirus (see page 399, column 1). The addition of a panel assay in the newly added claims does not provide a contribution over the prior art. It is obvious from the prior art that Rattanarithikuln et al. disclosed that they used two different monoclonal antibodies in an Elisa assay to differentiate whether the misquotes carries *P. vivax* or *P. falciparum.* Merely changing the format of an assay (vertical v. horizontal or PVDF v nitrocellulose) that depends on the same unique interaction between an antibody and the antigen for its functions does not distinguish the instant invention over the prior art. Therefore, the instant invention is obvious over Oprandy et al., Huang et al. and WHO Bulletin in view of Rattanarithikuln et al. and Sithiprasasna et al.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 5/19/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600